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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,858	03/02/2005	Hiroyoshi Hidaka	8279.829USWO	5428
7590	04/19/2006		EXAMINER	
Hamre Schumann Mueller & Larson P. C. P.O. BOX Minneapolis, MN 55402			GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/526,858	HIDAKA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Shirley V. Gembeh	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 02 February 2006.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-4, 9, 15, 16 and 24-27 is/are pending in the application.
  - 4a) Of the above claim(s) 5-8, 10-14 and 17-23 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 9, 15, 16 and 24-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

The response filed February 9, 2006 presents remarks and arguments to the office action mailed October 31, 2005. Applicant's request for reconsideration of the rejection of the claims in the last office action has been considered.

### **Status of claims**

Claims 1, 9, and 15-16 have been amended; claims 5-8, 10-14 and 17-23 have been cancelled; claims 24-27 are new and claims 1-4, 9, 15-16 and 24-27 are pending.

### **Response to Amendment**

In response to the Office Action dated October 31, 2005, Applicant has provided arguments for the patentability of claims 1-25.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

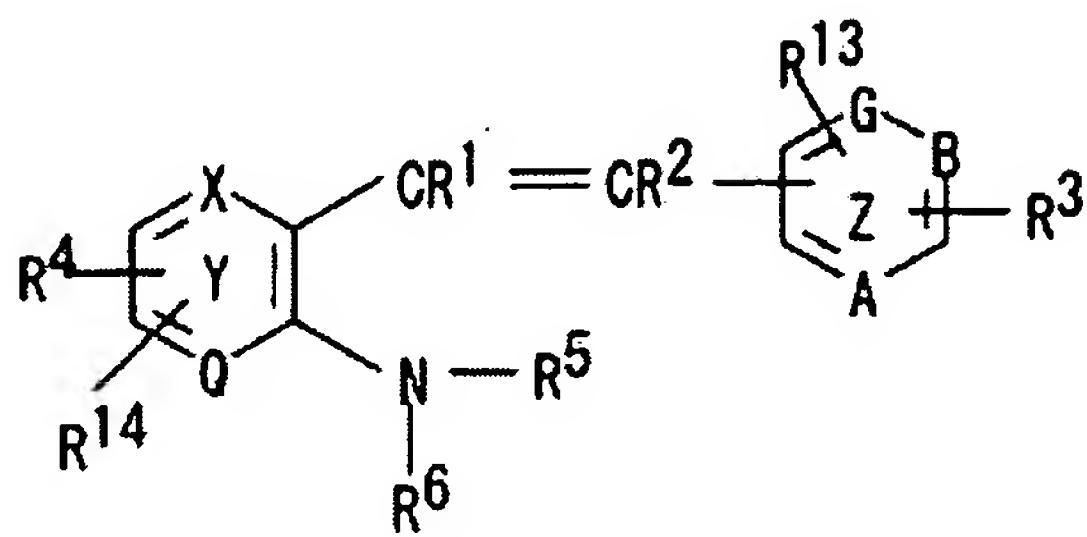
### ***Claim Rejections - 35 USC § 102***

Applicant's arguments, see page 11, filed February 9<sup>th</sup> 2006, with respect to claim rejection under 35 U.S.C 102 have been fully considered and are persuasive. The rejection has been withdrawn.

### ***Claim Rejections - 35 USC § 103***

I. Claims 1-4 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al., US 5,972,976 in view of Goodman and Gilman, The Pharmacological Basis of therapeutics and Ragaz et al., The new England J. of Med.

Hidaka et al teach a pharmaceutical composition for treating malignant tumor (see col. 1 lines 13+) with a compound of formula I in current claim 1



(1)

(see col. 2 lines 15+), wherein the of

Rs' are the same as claimed by applicant (see col. 2 lines 25-60), wherein R<sup>1</sup> and R<sup>2</sup> each represent hydrogen (see col. 2 lines 26-27) as in current claims 2 and 3. R<sup>3</sup>, R<sup>4</sup>, R<sup>13</sup> and R<sup>14</sup> is recited (see col. 2 lines 30), R<sup>5</sup> is hydrogen (see col. 2 line 39), R<sup>6</sup> is phenylsulfonyl (see col. 2 lines 46+), Ring Y is phenyl and Ring Z is 4-pyridyl (see col. 2 lines 38+) as in current claim 2, wherein R<sup>1</sup> and R<sup>2</sup> each represents hydrogen (see col. 2 line 26-27), R<sup>3</sup>, R<sup>4</sup>, R<sup>13</sup> and R<sup>14</sup> represents hydrogen (see col. 3 line 47), R<sup>5</sup> is hydrogen (see col. 2 line 39), R<sup>6</sup> is phenylsulfonyl (see col. 2 lines 46+), Ring Y is phenyl and Ring Z is 4-pyridyl (see col. 2 lines 38+) as in current claim 3, wherein the pharmaceutical composition of formula 1 is

(E)-4-[2-[2-[N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]ethenyl]pyridine, (see col. 4 line 53) as in current claim 4.

Goodman and Gilman teach an antitumor agent is cisplatin a platinum compound at page 1269, wherein the composition contains another antitumor compound, as in instant claims 1-4 (see page 1270).

Although the references, Goodman et al., did not teach using the specific compound of formula I with the cisplatin, the idea of combination therapy to treat tumors has been in effect a long time.

One of ordinary skill in the art would have known to combine the teachings of Hidaka in view of Goodman treat tumors using adjuvant radiotherapy and chemotherapy wherein the drugs of Hidaka with that of Goodman are used, and expect a successful result. The drug of Hidaka is a well known anti cancer drug and when combined with other drugs of anticancer effect a synergistic effect is seen (see page 1230 of Goodman).

Thus, the claimed invention was *prima facia* obvious to make and use at the time it was made.

Applicant Traverse: that the pharmaceutical composition for treating a malignant tumor should include both formula I and another anti-tumor agent (see page 11 of Applicants' response).

In response, in the office action it was shown that the drug by Hidaki is capable of being used with another antitumor drug by combining the reference of Hidaki with that of Goodman et al. Also note that In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

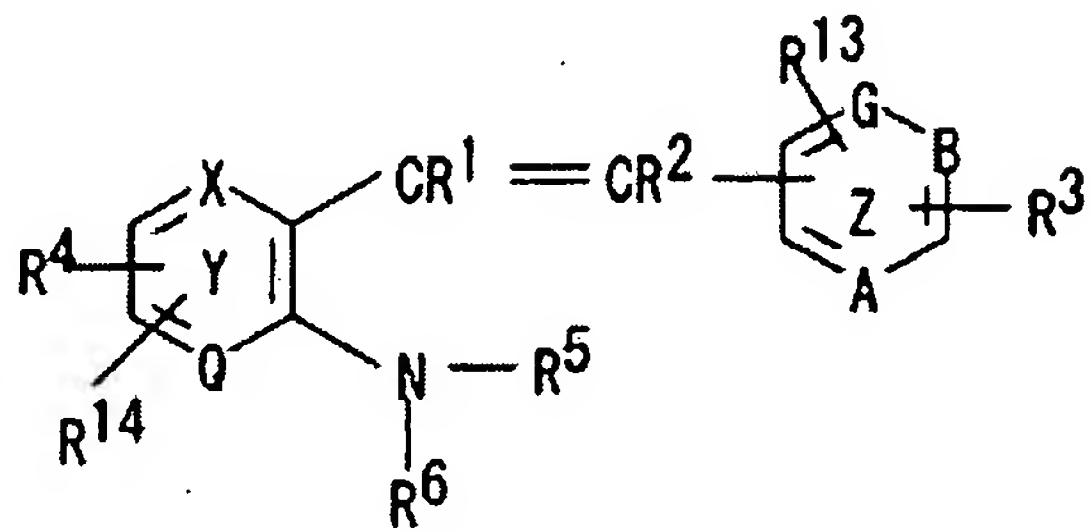
1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Goodman et al clearly teach using cisplatin a anti cancer drug with another anti tumor drug.

Applicant's arguments have been fully considered but they are not persuasive. Because as cited in the office action dated October 31, 2005, page 5, the Goodman reference clearly teach administering cisplatin with another anti-tumor drug for a synergistic effect in treating malignant tumor. The anti-tumor drug is any drug that has antitumor activity or has been used to treat malignant tumor is capable of being employed for a combination treatment. Clearly the compound of formula I is an anti-tumor drug and falls within that scope of teaching of Goodman et al.

The claim rejection is maintained for the reasons set forth in the office action mailed October 31, 2005.

II. Claims 15-16 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al., US 5,972,976 in view of Goodman and Gilman, The Pharmacological Basis of therapeutics Ragaz et al., The new England J. of Med. as applied to claims 1-4 and 24.

Hidaka et al teach a pharmaceutical composition for treating malignant tumor (see col. 1 lines 13+) with a compound of formula I in current claims 15-16 and 26-27



(I)

(see col. 2 lines 15+), wherein the of

Rs' are the same as claimed by applicant (see col. 2 lines 25-60), wherein R<sup>1</sup> and R<sup>2</sup> each represent hydrogen (see col. 2 lines 26-27) as in current claims 2 and 3. R<sup>3</sup>, R<sup>4</sup>, R<sup>13</sup> and R<sup>14</sup> is recited (see col. 2 lines 30), R<sup>5</sup> is hydrogen (see col. 2 line 39), R<sup>6</sup> is phenylsulfonyl (see col. 2 lines 46+), Ring Y is phenyl and Ring Z is 4-pyridyl (see col. 2 lines 38+) as in current claim 2, wherein R<sup>1</sup> and R<sup>2</sup> each represents hydrogen (see col. 2 line 26-27), R<sup>3</sup>, R<sup>4</sup>, R<sup>13</sup> and R<sup>14</sup> represents hydrogen (see col. 3 line 47), R<sup>5</sup> is hydrogen (see col. 2 line 39), R<sup>6</sup> is phenylsulfonyl (see col. 2 lines 46+), Ring Y is phenyl and Ring Z is 4-pyridyl (see col. 2 lines 38+).

Although the references, Goodman et al., did not teach using the specific compound of formula I with the cisplatin, the idea of combination therapy to treat tumors has been in effect a long time.

One of ordinary skill in the art would have known to combine the teachings of Hidaka in view of Goodman treat tumors using adjuvant radiotherapy and chemotherapy wherein the drugs of Hidaka with that of Goodman are used, and expect a successful result. The drug of Hidaka is a well known anti cancer drug and when combined with

other drugs of anticancer effect a synergistic effect is seen (see page 1230 of Goodman).

Thus, the claimed invention was *prima facia* obvious to make and use at the time it was made.

**Applicant Traverse:** that the pharmaceutical composition for treating a malignant tumor should include both formula I and another anti-tumor agent (see page 11 of Applicants' response

In response Applicants argument has been fully considered but are not persuasive for the same reasons set forth above. See *supra*.

**With regard to the kit claims 9 and 25:**

Claims 9 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al., US 5,972,976 in view of Goodman and Gilman, The Pharmacological Basis of therapeutics Ragaz et al., The new England J. of Med. as applied to claims 1-4, 24 and 15-16 and 26-27.

In addition, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container.

**Applicant Traverse:** that the pharmaceutical composition for treating a malignant tumor should include both formula I and another anti-tumor agent (see page 11 of Applicants' response

In response Applicants argument has been fully considered but are not persuasive for the same reasons set forth above. See supra.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG  
4/13/06

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